510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K040174

B. Purpose for Submission:
Addition of bilirubin parameter on the Omni S Analyzer

C. Analyte:
Bilirubin (total & unbound) in neonate test system

D. Type of Test:
Quantitative

E. Applicant:
Roche Diagnostics Corporation

F. Proprietary and Established Names:
Bilirubin Assay on the OMNI S Analyzer

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1113
2. Classification:
   I
3. Product Code:
   MQM
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   The Roche Diagnostics OMNI S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, bilirubin, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

2. Indication(s) for use:
   The Roche Diagnostics OMNI S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN,

bilirubin, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

3. Special condition for use statement(s):
   Prescription use

4. Special instrument Requirements:
   OMNI S Analyzer (K032311)

I. Device Description:

Refer to K032311 for details on the fully automated OMNI S instrument. Contained within the instrument is the oximeter module, an optical sensor module that is used for determining bilirubin.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Radiometer ABL735
2. Predicate K number(s):
   K991417
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quantitative determination of neonatal bilirubin in newborns using whole blood samples	Quantitative determination of neonatal bilirubin in newborns using whole blood samples
Technology	Automated co-oximetry	Automated co-oximetry
Differences		
Item	**Device**	**Predicate**
Instrument	OMNI S	ABL735

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Bilirubin is measured spectrophotometrically on the basis of Lambert-Beer's law.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Precision was evaluated using Autotrol Plus Levels 1-3, 4B and 5B, and three levels of whole blood, forty (40) runs each. The Autotrol levels ranged between 4 and 24 mg/dL. The whole blood levels

ranged between 8 and 44 mg/dL. The CVs for the Autotrol materials were ≤1.67%. The CVs for the human whole blood were ≤7.56%.

b. Linearity/assay reportable range:
The assay reportable range is 3-50 mg/dL. Linearity was evaluated using human whole blood (3 measurements per level) and two OMNI S instruments. The mean values ranged from 6.86 to 41.52 mg/dL, and the recovery ranged from 93.85 to 114.33%. The correlation results were as follows: slope (0.9038-1.1064), intercept (+/-1.514), and correlation coefficient (0.9996).

c. Traceability (controls, calibrators, or method):
Refer to K032311.

d. Detection limit:
The detection limit is 3 mg/dL. This is supported in various method comparison and verification studies.

e. Analytical specificity:
Interference studies were performed on methylene blue, Intralipid, Lipofundin (triglyceride), Propofol, Indocyanine, Beta-carotin, and Evans Blue. Hemoglobin interference was deemed unnecessary due to the design of the instrument. The measured concentration of hemoglobin derivatives is used to provide a bilirubin measurement virtually free of interference from hemoglobin.

The interference studies were performed according to NCCLS Document EP7-P "Interference Testing in Clinical Chemistry." The analysis performed on all potential interfering substances was the control group bias versus the reference value. Methylene blue was found to be an interferent.

f. Assay cut-off:
See Detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:
The bilirubin assay on the OMNI S analyzer was compared to four commercially available methods and yielded the following results:

Comparison method	**N**	**Slope and Intercept**	**Bias**	**R value**
Hitachi TBil	85	y =0.968x – 0.127	-3.7%	0.986
Beckman LX 20 tBil	76	y = 1.060x – 0.537	+1.4%	0.980
Kodak Vitros tBil	73	y = 0.988x - 0.119	-2.4%	0.984
Radiometer	82	y = 1.044x + 0.327	+10.5%	0.974

b. Matrix comparison:
Not applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable

   b. Clinical specificity:
   Not applicable

   c. Other clinical supportive data (when a and b are not applicable):
   Not applicable

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   The expected values/reference ranges were established based on the literature. Specific reference was made to Tietz "Textbook of Clinical Chemistry" 3rd Edition 1999.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.